



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2020-0607; FRL-9454-01-OCSP]

### Fluopyram; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation amends tolerances for residues of fluopyram in or on cereal grain crop group 15 (except corn and rice), rapeseed subgroup 20A, and multiple animal commodities, which are identified and discussed later in this document. This regulation also establishes an import tolerance for residues of fluopyram in or on coffee. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2020-0607, is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is open to visitors by appointment only. For the latest status information on EPA/DC services and access, visit <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT: Marietta Echeverria**, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDFRNotices@epa.gov](mailto:RDFRNotices@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them.

Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

#### *B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at <https://www.ecfr.gov/current/title-40>.

#### *C. How Can I File an Objection or Hearing Request?*

Under FFDCFA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You

must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2020-0607 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2020-0607, by one of the following methods:

- *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

## **II. Summary of Petitioned-For Tolerance**

In the *Federal Register* of February 25, 2021 (86 FR 11488) (FRL-10020-47), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F8855) by Bayer CropScience, 800 N Lindbergh Blvd., St. Louis, MO 63167. The petition requested that 40 CFR 180.661(a)(1) be amended by establishing a tolerance for residues of the fungicide fluopyram, *N*-[2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]ethyl]-2-(trifluoromethyl)benzamide, in or on the following raw agricultural commodity: Coffee at 0.03 parts per million (ppm). The petition also requested to amend tolerances in 40 CFR 180.661(a)(1) for residues of the fungicide fluopyram in or on the following raw agricultural commodities: Grain, cereal, group 15, except corn and rice at 0.5 ppm; and Rapeseed subgroup 20A at 0.3 ppm. In addition, the petition requested to amend tolerances in 40 CFR 180.661(a)(2) for residues of the fungicide fluopyram in or on the following animal commodities: Cattle, fat at 0.60 ppm; Cattle, meat at 0.60 ppm; Cattle, meat byproducts at 6.0 ppm; Egg at 0.06 ppm; Goat, fat at 0.60 ppm; Goat, meat at 0.60 ppm; Goat, meat byproducts at 6.0 ppm; Hog, fat at 0.01 ppm; Hog, meat at 0.01 ppm; Hog, meat byproducts at 0.06 ppm; Horse, fat at 0.60 ppm; Horse, meat at 0.60 ppm; Horse, meat byproducts at 6.0 ppm; Poultry, fat at 0.03 ppm; Poultry, meat at 0.03 ppm; Poultry, meat byproducts at 0.10 ppm; Sheep, fat at 0.60 ppm; Sheep, meat at 0.60 ppm; and Sheep, meat byproducts at 6.0 ppm. That document referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, <https://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is establishing and amending, in accordance with section 408(d)(4)(a)(i), tolerances that vary in some respects from what the petitioner requested. The reasons for these changes are explained in Unit IV.D.

### III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fluopyram including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluopyram follows.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings and republishing the same sections is unnecessary. EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published a number of tolerance rulemakings for fluopyram, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to fluopyram and established tolerances for residues of that chemical. EPA is incorporating previously published sections from those rulemakings as described further in this rulemaking, as they remain unchanged.

*Toxicological profile.* For a discussion of the Toxicological Profile of fluopyram, see Unit III.A. of the July 1, 2019, rulemaking (84 FR 31208) (FRL-9994-36).

*Toxicological points of departure/Levels of concern.* For a summary of the Toxicological Points of Departure/Levels of Concern used for the safety assessment, see Unit III.B. of the July 1, 2019, rulemaking.

*Exposure assessment.* Much of the exposure assessment remains the same, although updates have occurred to accommodate exposures from the petitioned-for tolerances. The updates are discussed in this section; for a description of the rest of the EPA approach to and assumptions for the exposure assessment, see Unit III.C. of the July 1, 2019, rulemaking.

EPA's dietary exposure assessments have been updated to include: the reduced exposure from the revised uses (lower maximum application rates) of fluopyram on cereal grain crop group 15 (except corn and rice) and rapeseed subgroup 20A; the reduced anticipated residues in livestock commodities; and the additional exposure associated with the import tolerance on coffee. For the acute dietary exposure assessment, EPA used the highest average field trial concentrations for coffee, cereal grain group 15, and rapeseed 20A. All other commodities used tolerance-level residues. The acute analysis used 100 percent crop treated (PCT) for all commodities. For the chronic dietary exposure assessment, EPA used field trial mean residue values and incorporated the same PCT data that were used in the July 1, 2019, rulemaking for existing uses, as well as

chronic refined inputs to the livestock anticipated residues of field trial median data. EPA assumed 100 PCT for coffee, cereal grain crop group 15 (except corn and rice), and rapeseed subgroup 20A.

*Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data calls as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, and the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the average PCT for existing uses for the chronic dietary exposure assessment as follows: Almonds, 20%; apples, 25%; apricots, 5%; artichoke, 15%; broccoli, 2.5%; cabbage, 2.5%; carrots, 1%; cauliflower, 1%; cherries, 25%; cotton, 1%; dry beans and peas, 1%; grapefruit, 10%; grapes, raisins, 1%; table grapes, 5%; wine grapes, 20%; lemons, 1%; lettuce, 1%; onions, 1%; oranges, 15%; peaches, 1%; peanuts, 2.5%; pears, 5%; peppers, 5%; pistachios, 15%; potatoes, 20%; strawberries, 10%; tomatoes, 1%; walnuts, 10%; and watermelons, 15%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) for the chemical/crop combination for the most recent 10 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5%. In those cases, the Agency would use <1% or <2.5% as the average PCT value, respectively. The maximum PCT figure is the highest observed maximum value reported within the recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case, the Agency uses <2.5% as the maximum PCT.

The Agency believes that the three conditions discussed earlier have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for

significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which fluopyram may be applied in a particular area.

*Drinking water, non-occupational, and cumulative exposures.* Drinking water exposures and residential (non-occupational) exposures are not impacted by the revised uses and import tolerance in this action, and thus have not changed from the July 1, 2019, rulemaking. Fluopyram is currently registered for use on golf course turf, residential lawns, fruit trees, nut trees, ornamentals and gardens that could result in residential exposures. The most conservative residential risk estimates that were used in the aggregate assessment are adult handler inhalation exposures from treating lawns with a hose-end spray and incidental oral hand-to-mouth post-application exposure to treated lawns for children aged 1 to less than 2 years old. EPA's conclusions concerning cumulative risk remain unchanged from the July 1, 2019, rulemaking.

*Safety factor for infants and children.* EPA continues to conclude that there is reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor. See Unit III.D. of the July 1, 2019, rulemaking for a discussion of the Agency's rationale for that determination.

*Aggregate risks and determination of safety.* EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic population adjusted (cPAD).

For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists.

Acute dietary risks are below the Agency's level of concern of 100% of the aPAD; they are 24% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD; they are 78% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

As explained in the July 1, 2019, rule, the Agency analyzed short-term inhalation exposure to residential handlers and short-term incidental oral hand-to-mouth post-application exposure to children 1 to 2 years old on treated lawns. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 1,500 for both adults (using a residential handler exposure scenario) and post-application exposure to children 1 to 2 years old. Because EPA's level of concern for fluopyram is an MOE of 100 or below, these MOEs are not of concern.

As stated in the July 1, 2019, rule, fluopyram is not registered for any use patterns that would result in intermediate-term residential exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has been assessed under the appropriately protective cPAD, EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for fluopyram.

Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, fluopyram is not expected to pose a cancer risk to humans.

Therefore, based on the risk assessments and information described above, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to fluopyram residues. More detailed information can be found at <https://www.regulations.gov> in the document titled “Fluopyram. Human Health Risk Assessment for the Revision of Permanent Tolerances and Registration for Use on Cereal Grain Crop Group 15 and Rapeseed Subgroup 20A, and for the Establishment of Permanent Tolerance without U.S. Registration for Residues in/on Coffee Commodities” in docket ID number EPA-HQ-OPP-2020-0607.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

For a discussion of the available analytical enforcement method, see Unit IV.A. of the July 1, 2019, rulemaking.

##### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDC section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDC section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for fluopyram in or on canola at 1 ppm and rye grain and wheat grain both at 0.9 ppm. EPA is not harmonizing the U.S. tolerances for

rapeseed subgroup 20A and crop group 15 (except rice and corn) with the Codex MRLs for canola, rye grain, or wheat grain because the U.S. tolerances are being harmonized with the Canadian MRLs as part of a joint review with the U.S.'s major trading partner.

The Codex has also established MRLs for fluopyram in or on milk at 0.8 ppm, cattle fat at 1.5 ppm, cattle meat at 1.5 ppm, cattle meat byproducts at 8 ppm, hog fat at 1.5 ppm, hog meat at 1.5 ppm, hog meat byproducts at 8 ppm, eggs at 2 ppm, poultry fat at 1 ppm, poultry meat at 1.5 ppm and poultry, kidney and poultry, liver at 5 ppm. To be consistent with Canada, EPA is not harmonizing the U.S. tolerances for milk, cattle fat, cattle meat, cattle meat byproducts, hog fat, hog meat, hog meat byproducts, eggs, poultry fat, poultry meat, and poultry meat byproducts with the Codex MRLs above. The U.S. and Canada are jointly reviewing the revised use pattern in the fluopyram petition. Because the maximum application rates for livestock feed items (rapeseed subgroup 20A and cereal grains group 15 (except corn and rice)) are being reduced in both countries, the tolerances on both plant and livestock commodities are being decreased in both countries.

Codex has not established an MRL for residues of fluopyram in or on coffee commodities.

### *C. Response to Comments*

Two comments were submitted to the docket in response to the February 25, 2021 Notice of Filing. Although the Agency recognizes that some individuals believe that pesticides should be banned on agricultural commodities, the existing legal framework provided by section 408 of the FFDCA authorizes EPA to establish tolerances when it determines that the tolerance is safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCA requires EPA to consider, EPA has determined that the fluopyram tolerances are safe. The commenters have provided no information indicating that a safety determination cannot be supported.

### *D. Revisions to Petitioned-For Tolerances*

The commodity definition for coffee is revised to coffee, green beans and the tolerance is established at 0.03 ppm to reflect the OECD rounding class.

Livestock tolerances are revised based upon expected secondary residues using the more reasonably balanced diet (MRBD) calculations and incorporating observed transfer factors. The petition states that the proposed cattle tolerances should be extended to all ruminants; however, those tolerances should be individually revised. Therefore, tolerances are amended for cattle, meat at 0.3 ppm; cattle, fat at 0.3 ppm; cattle, meat byproducts at 3 ppm; horse, meat at 0.3 ppm; horse, fat at 0.3 ppm; horse, meat byproducts at 3 ppm; goat, meat at 0.3 ppm; goat, fat at 0.3 ppm; goat, meat byproducts at 3 ppm; sheep, meat at 0.3 ppm; sheep, fat at 0.3 ppm; sheep, meat byproducts at 3 ppm; and hog, meat byproducts at 0.04 ppm. Tolerances are amended for egg at 0.03 ppm; poultry, meat at 0.02 ppm; poultry, fat at 0.01 ppm; and poultry, meat byproducts at 0.06 ppm. The Agency is also amending the tolerance for milk at 0.15 ppm.

## **V. Conclusion**

Therefore, a tolerance is established for residues of fluopyram, *N*-[2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]ethyl]-2-(trifluoromethyl)benzamide, in or on coffee, green beans at 0.03 ppm, and existing tolerances are amended to the following levels: grain, cereal, group 15, except corn and rice at 0.5 ppm; rapeseed subgroup 20A at 0.3 ppm; cattle, fat at 0.3 ppm; cattle, meat at 0.3 ppm; cattle, meat byproducts at 3 ppm; egg at 0.03 ppm; goat, fat at 0.3 ppm; goat, meat at 0.3 ppm; goat, meat byproducts at 3 ppm; hog, fat at 0.01 ppm; hog, meat at 0.01 ppm; hog, meat byproducts at 0.04 ppm; horse, fat at 0.3 ppm; horse, meat at 0.3 ppm; horse, meat byproducts at 3 ppm; milk at 0.15 ppm; poultry, fat at 0.01 ppm; poultry, meat at 0.02 ppm; poultry, meat byproducts at 0.06 ppm; sheep, fat at 0.3 ppm; sheep, meat at 0.3 ppm; sheep, meat byproducts at 3 ppm. For transparency, the following list identifies the established tolerances that are being amended to the levels listed above: grain, cereal, group 15, except corn and rice at 4.0

ppm; rapeseed subgroup 20A at 5.0 ppm; cattle, fat at 0.70 ppm; cattle, meat at 0.80 ppm; cattle, meat byproducts at 7.5 ppm; egg at 0.08 ppm; goat, fat at 0.70 ppm; goat, meat at 0.80 ppm; goat, meat byproducts at 7.5 ppm; hog, fat at 0.20 ppm; hog, meat at 0.02 ppm; hog, meat byproducts at 0.20 ppm; horse, fat at 0.70 ppm; horse, meat at 0.80 ppm; horse, meat byproducts at 7.5 ppm; milk at 0.40 ppm; poultry, fat at 0.04 ppm; poultry, meat at 0.04 ppm; poultry, meat byproducts at 0.20 ppm; sheep, fat at 0.70 ppm; sheep, meat at 0.80 ppm; and sheep, meat byproducts at 7.5 ppm.

## **VI. Statutory and Executive Order Reviews**

This action establishes tolerances under FFDCa section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCa section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCa section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

## **VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

## **List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 11, 2022.

**Catherine Aubee,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

**PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In § 180.661:

a. Amend paragraph (a)(1) by:

i. Designating the table as Table 1 to Paragraph (a)(1)”;

ii. Adding in alphabetical order the entry “Coffee, green beans”; and

iii. Revising the entries “Grain, cereal, group 15, except corn and rice” and “Rapeseed subgroup 20A”;

b. Amend paragraph (a)(2) by:

i. Designating the table as Table 2 to Paragraph (a)(2); and

ii. Revising newly designated Table 2.

The additions and revisions read as follows:

**§ 180.661 Fluopyram; tolerances for residues.**

(a) \* \* \*

(1) \* \* \*

Table 1 to Paragraph (a)(1)

Commodity	Parts per million
* * * *	* * *
Coffee, green beans <sup>2</sup>	0.03
* * * *	* * *
Grain, cereal, group 15, except corn and rice	0.5

* * * * *
Rapeseed subgroup 20A <span style="float: right;">0.3</span>
* * * * *

\* \* \* \* \*

<sup>2</sup> There are no U.S. registrations on coffee, green beans as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

(2) \* \* \*

Table 2 to Paragraph (a)(2)

Commodity	Parts per million
Cattle, fat	0.3
Cattle, meat	0.3
Cattle, meat byproducts	3
Egg	0.03
Goat, fat	0.3
Goat, meat	0.3
Goat, meat byproducts	3
Hog, fat	0.01
Hog, meat	0.01
Hog, meat byproducts	0.04
Horse, fat	0.3
Horse, meat	0.3
Horse, meat byproducts	3
Milk	0.15
Poultry, fat	0.01
Poultry, meat	0.02
Poultry, meat byproducts	0.06
Sheep, fat	0.3
Sheep, meat	0.3
Sheep, meat byproducts	3

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